

WE CLAIM:

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1. An apparatus for dilating and delivering a medicament to an obstruction within a vascular segment or a body passageway which comprises:

a catheter having a distal end and a proximal end;

10 a substantially cylindrical shaped expansion member located on said distal end of said catheter, said expansion member having a first end and a second end, said first end being a distance from said second end;

15 an altering means engagable to said first end and said second end of said expansion member for altering said first distance therebetween to move said expansion member between a first configuration wherein said expansion member is characterized by a first diameter and a second configuration wherein said expansion member is 20 characterized by a second diameter, said second diameter being greater than said first diameter; and

25 a therapeutic agent or medicament coated on at least a portion of said expansion member.

30 2. An apparatus as recited in claim 1 wherein said expansion member defines a flow passageway extending between said first end and said second end of the expansion member.

35 3. An apparatus as recited in claim 1 wherein said expansion member comprises a first plurality of flexible elongate elements helically wound in a first direction of rotation and a second plurality of flexible elongate

elements helically wound in a second direction of rotation to form a braid.

4. An apparatus as recited in claim 1 wherein said expansion member is adapted to allow blood perfusion while said expansion member is either in said first diameter or in said second diameter.

5. An apparatus as recited in claim 1 wherein said therapeutic agent or medicament is incorporated into a non-therapeutic substrate.

6. An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is an anticoagulant selected from the group consisting of D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, an antithrombin compound, a platelet receptor antagonist, an anti-thrombin antibody, an anti-platelet receptor antibody, hirudin, hirulog, phe-pro-arg-chloromethyketone (Ppack), Factor VIIa, Factor Xa, aspirin, clopridogrel, ticlopidine, a prostaglandin inhibitor, a platelet inhibitor and a tick anti-platelet peptide, and combinations thereof.

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7. An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is a promoter of vascular cell growth selected from the group consisting of a growth factor stimulator, a growth factor receptor agonist, a transcriptional activator, and a translational promoter, and combinations thereof.

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8. An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is an inhibitor of vascular cell growth selected from the group consisting of a growth factor inhibitor, a growth factor receptor antagonist, a transcriptional repressor, a translational repressor, an antisense DNA, an antisense RNA, a replication inhibitor, an inhibitory antibody, an antibody directed against growth factors, a bifunctional molecule consisting of a growth factor and a cytotoxin, and a bifunctional molecule consisting of an antibody and a cytotoxin, double stranded DNA, single stranded DNA, single stranded RNA and a double stranded RNA and combinations thereof.
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9. An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is selected from the group consisting of a cholesterol-lowering agent, a vasodilating agent, and agents which interfere with endogenous vasoactive mechanisms, estrogen, testosterone, steroid hormones, cortisol, dexamethasone, corticosteroids, thyroid hormones, thyroid hormones analogs, thyroid hormones antagonist, adrenocorticotropic hormone, thyroid stimulating hormone, thyroid releasing factor, thyroid releasing factor analogs, thyroid releasing factor antagonists and combinations thereof.
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10. An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is a smooth muscle inhibitor selected from the group consisting of an agent that modulates intracellular calcium binding proteins, a receptor blocker for contractile agonists, an inhibitor of the sodium/hydrogen antiporter, a protease inhibitor, a nitrovasodilator, a phosphodiesterase inhibitor, a
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phenothiazine, a growth factor receptor agonist, an anti-mitotic agent, an immunosuppressive agent, and a protein kinase inhibitor, and combinations thereof.

5 11. An apparatus as recited in claim 1, wherein said therapeutic agent or medicament is a compound that inhibits cellular proliferation, Paclitaxel, Rapamycin, Sirolimus, Actinomycin D, Methotrexate, Doxorubicin, cyclophosphamide, 10 and 5-fluorouracil, and combinations thereof.

15 12. An apparatus as recited in claim 1 further comprising a plurality of therapeutic agents or medicaments coated on at least a portion of said expansion member.

20 13. An apparatus as recited in claim 1, further comprising a lumen extending throughout the longitudinal length of said catheter, said lumen having a distal end that terminates within said expansion member, said lumen capable 25 of delivering a medicament.

25 14. An apparatus for dilating and delivering a medicament to an obstruction within a vascular segment or a body passageway which comprises:

 a catheter having a distal end and a proximal end;

30 a substantially cylindrical shaped expansion member located on said distal end of said catheter, said expansion member having a first end and a second end, said first end being a distance from said second end;

35 an altering means engagable to said first end and said second end of said expansion member for altering said first

distance therebetween to move said expansion member between a first configuration wherein said expansion member is characterized by a first diameter and a second configuration wherein said expansion member is characterized by a second diameter, said second diameter being greater than said first diameter;

one or more electrical leads extending throughout the longitudinal length of said catheter and engaged to said expansion member; and

a medicament coated on said expansion member.

15. An apparatus as recited in claim 14 wherein said expansion member defines a flow passageway extending between said first end and said second end of the expansion member.

20. An apparatus as recited in claim 14 wherein said expansion member comprises a first plurality of flexible elongate elements helically wound in a first direction of rotation and a second plurality of flexible elongate elements helically wound in a second direction of rotation to form a braid.

25. An apparatus as recited in claim 14 wherein said expansion member is adapted to allow blood perfusion while said expansion member is either in said first diameter or in said second diameter.

30. An apparatus as recited in claim 14 wherein said therapeutic agent or medicament is incorporated into a non-therapeutic substrate.

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19. An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is an anticoagulant selected from the group consisting of D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, an antithrombin compound, a platelet receptor antagonist, an anti-thrombin antibody, an anti-platelet receptor antibody, hirudin, hirulog, phe-pro-arg-chloromethyketone (Ppack), Factor VIIa, Factor Xa, aspirin, clopridogrel, ticlopidine, a prostaglandin inhibitor, a platelet inhibitor and a tick anti-platelet peptide, and combinations thereof.
- 15 20. An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is a promoter of vascular cell growth selected from the group consisting of a growth factor stimulator, a growth factor receptor agonist, a transcriptional activator, and a translational promoter, and combinations thereof.
- 20 25 30 35 21. An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is an inhibitor of vascular cell growth selected from the group consisting of a growth factor inhibitor, a growth factor receptor antagonist, a transcriptional repressor, a translational repressor, an antisense DNA, an antisense RNA, a replication inhibitor, an inhibitory antibody, an antibody directed against growth factors, a bifunctional molecule consisting of a growth factor and a cytotoxin, and a bifunctional molecule consisting of an antibody and a cytotoxin, double stranded DNA, single stranded DNA, single stranded RNA and a double stranded RNA and combinations thereof.

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22. An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is selected from the group consisting of a cholesterol-lowering agent, a vasodilating agent, and agents which interfere with endogenous vasoactive mechanisms, estrogen, testosterone, steroid hormones, cortisol, dexamethasone, corticosteroids, thyroid hormones, thyroid hormones analogs, thyroid hormones antagonist, adrenocorticotropic hormone, thyroid stimulating hormone, thyroid releasing factor, thyroid releasing factor analogs, thyroid releasing factor antagonists and combinations thereof.
23. An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is a smooth muscle inhibitor selected from the group consisting of an agent that modulates intracellular calcium binding proteins, a receptor blocker for contractile agonists, an inhibitor of the sodium/hydrogen antiporter, a protease inhibitor, a nitrovasodilator, a phosphodiesterase inhibitor, a phenothiazine, a growth factor receptor agonist, an antimitotic agent, an immunosuppressive agent, and a protein kinase inhibitor, and combinations thereof.
24. An apparatus as recited in claim 14, wherein said therapeutic agent or medicament is a compound that inhibits cellular proliferation, Paclitaxel, Rapamycin, Sirolimus, Actinomycin D, Methotrexate, Doxorubicin, cyclophosphamide, and 5-fluorouracil, and combinations thereof.
25. An apparatus as recited in claim 14, further comprising a lumen extending throughout the longitudinal length of said catheter, said lumen having a distal end

that terminates within said expansion member, said lumen capable of delivering a medicament.

- 5 26. An apparatus as recited in claim 14, further comprising a plurality of therapeutic agents or medicaments coated on at least a portion of said expansion member.
- 10 27. An apparatus as recited in claim 14, wherein said electrical leads can communicate electrical energy to said expansion member to compel said medicament or therapeutic agent into target tissues by iontophoretic means.
- 15 28. An apparatus as recited in claim 14, wherein said electrical leads can communicate electrical energy to said expansion member to compel electroporation transfer of said medicament or therapeutic agent into target tissues.
- 20 29. An apparatus as recited in claim 14, wherein said electrical leads can communicate electrical energy to said expansion member to cause both iontophoretic and electroporation transfer of said medicament or therapeutic agent into target tissues.
- 25 30. An apparatus as recited in claim 14, wherein said electrical leads can communicate electrical energy to said expansion member to cause said medicament or therapeutic agent to electrically bond to said expansion member.
- 30 31. A mechanical dilatation and medicament delivery device comprising:

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a catheter having a distal end and a proximal end,
said catheter having one or more lumens;

an expandable mesh positioned on said distal end
5 adapted to dilate an obstruction in a vessel, said mesh
having a first contracted diameter and a second expanded
diameter, said second expanded diameter being larger than
said first contracted diameter; and

10 said mechanical dilatation and medicament delivery
device being adapted to dilate said obstruction and expose
said obstruction to a medicament while allowing blood or
bodily fluids to flow through said expandable mesh.

15 32. A method for dilating and delivering a medicament to
an obstruction in a body passageway which comprises the
steps of:

advancing a mechanical dilatation catheter to a
20 predetermined site with a body passageway, said catheter
having an substantially cylindrical expansion member coated
with a medicament, said expansion member being moveable
between a first contracted configuration wherein said
expansion member is defined by a first dimension extending
25 in a radial direction, and a second expanded configuration
wherein said member is defined by a second dimension
extending in said radial direction;

applying a force on said coated expansion member in an
30 axial direction to move said expansion member between said
first contracted configuration to said second expanded
configuration wherein said expansion member dilates said
obstruction or body passageway and delivers the medicament
to an said obstruction or body passageway.

33. A method as recited in claim 32 which further comprises the step of positioning a guidewire in the body passageway, and wherein said advancing step is accomplished by threading said expansion member over said guidewire.

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34. A method as recited in claim 32 which further comprises the step of allowing said expansion member to be in said second expanded configuration for a predetermined period of time after the dilatation step to further expose
10 said obstruction to the medicament.

35. A method for dilating and delivering a medicament to an obstruction in a body passageway which comprises the steps of:

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advancing a mechanical dilatation catheter to a predetermined site with a body passageway, said catheter having an expansion member coated with a medicament and a iontophoretic transport means, said expansion member being moveable between a first contracted configuration wherein
20 said member is defined by a first dimension extending in a radial direction, and a second expanded configuration wherein said member is defined by a second dimension extending in said radial direction;

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applying a force on said expansion member in an axial direction to move said expansion member between said first contracted configuration to said second expanded configuration wherein said obstruction is dilated;

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supplying a flow of electrical current to said iontophoretic means to deliver said medicament into said obstruction or body passageway.

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36. A method as recited in claim 35, which further comprises the step of positioning a guidewire in the body passageway, and wherein said advancing step is accomplished by threading said catheter over said guidewire.

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37. A method as recited in claim 35 which further comprises the step of allowing said expansion member to be in said second expanded configuration for a predetermined period of time after the dilatation step to further expose
10 said obstruction to the medicament.

38. A method as recited in claim 35 which further comprises the step of varying the electric current with time to provide a waveform that controls the rate of
15 iontophoretic transport of said medicament.

39. A method as recited in claim 35, further comprising, prior to advancing the catheter, the step of applying electrical energy to said expansion member to cause said
20 medicament or therapeutic agent to electrically bond to said expansion member.

40. A method for dilating and delivering a medicament to
25 an obstruction in a body passageway which comprises the steps of:

advancing a mechanical dilatation catheter to a predetermined site with a body passageway, said catheter
30 having an expansion member coated with a medicament and a electroporation transport means, said expansion member being moveable between a first contracted configuration wherein said member is defined by a first dimension extending in a radial direction, and a second expanded configuration wherein said member is defined by a second dimension extending in said radial direction;

applying a force on said expansion member in an axial direction to move said expansion member between said first contracted configuration to said second expanded configuration wherein said obstruction is dilated;

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supplying a flow of electrical current to said electroporation means to deliver said medicament into said obstruction or body passageway.

10 41. A method as recited in claim 40 which further comprises the step of positioning a guidewire in the body passageway, and wherein said advancing step is accomplished by threading said catheter over said guidewire.

15 42. A method as recited in claim 40 which further comprises the step of allowing said expansion member to be in said second expanded configuration for a predetermined period of time after the dilatation step to further expose said obstruction to the medicament.

20 43. A method as recited in claim 40 which further comprises the step of varying the electric current with time to provide a waveform that controls the rate of electroporation transport of said medicament.

25 44. A method as recited in claim 40, further comprising, prior to advancing the catheter, the step of applying electrical energy to said expansion member to cause said medicament or therapeutic agent to electrically bond to said expansion member.

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